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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/607,361	06/30/2000	Yasushi Shigemori	032735-003	9813

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/607,361

Applicant(s)

SHIGEMORI ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12, 13 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 13 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This office action is in response to an amendment filed 2/20/04. Claims 10-11 and 14-20 have been cancelled. Claims 2, 6, 8, 21 and 24 have been amended. Claims 1-9, 12-13 and 21-24 are pending in this application.

#### *Response to Amendment*

Any rejection of Record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicant's amendment and therefore, this action is not final.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 12-13 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **These are new rejections.**

Claims 1-6, 8-9, 12-13 and 21-24 are vague and indefinite in that the metes and bounds of "homologous recombinant protein" are unclear. It is unclear what a "homologous recombinant protein" is. Is it a homologous recombination protein or a protein recombinant protein that is homologous to another?

Claims 1-9, 12-13 and 23-24 recites the limitation "said other double stranded DNA" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-9, 12-13 and 23-24 are vague and indefinite in that the metes and bounds of "said double stranded DNA comprises a sequence that is homologous" to the single-stranded end are unclear. Firstly as there are two double stranded DNAs recited in the claim, it is unclear to which of the two this phrase refers. Secondly, the phrase implies that any dinucleotide within the double stranded DNA can be homologous to the single stranded end. It appears from the specification that applicants intend for sequences within the double stranded end to be homologous to the single stranded end. It would be remedial to recite, "said double-stranded end comprises sequences".

Claims 1-9, 12-13 and 23-24 recite the limitation "the DNA complex" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claims 2-5 are vague and indefinite in that the metes and bounds of "said three-stranded structure" in line 3 are unclear. As the circular DNA complex has three-stranded structures in two places, it is unclear whether the "said three-stranded structure" is one of the two or both. If it were both, it would be remedial to recite, "said three-stranded structures".

Claims 2-5 are vague and indefinite in that the metes and bounds of "respectively homologous" are unclear. It is unclear to what "respectively" is referring.

Claim 5 is vague and indefinite in that the metes and bounds of "competent cells" are unclear. Is the term "competent cells" used to denote cells competent for transformation or competent for some other function such as for replication?

Claims 5-6, 21 are vague and indefinite in that the metes and bounds of "confers the ability of auto-replicating" are unclear. It is unclear to what the DNA is conferring the ability of auto-replicating.

Claim 9 recites the limitation "the contact" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-9, 12-13 and 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Applicants recite a method of ligation using a genus of homologous recombinant proteins.

Applicants claim a genus of DNA sequences, which confer the ability to auto-replicate on the double stranded region of DNA (claims 5-6 and 21).

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

In the instant case, applicants recite a method for the ligation of a double stranded end of a double-stranded DNA and a single-stranded end of another double-stranded DNA in which a homologous recombination protein mediates the formation of a three-stranded structure. RecA alone is utilized in the instant specification to catalyze the formation of a three-stranded structure formed from the combination of homologous double-stranded ends and single-stranded ends. While numerous proteins mediate homologous recombination, it is unclear whether any of these recombination proteins catalyze the instantly recited reaction. Neither the prior art nor the specification teaches that any of these proteins other than recA are able to mediate the formation of triple-stranded DNA complexes. Given the large size and diverse nature of "homologous recombination proteins" and the inability to determine which will also possess the ability to mediate the formation of three-stranded formation during recombination, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

In the instant case, applicants do not disclose any DNA sequences that can confer the ability to auto-replicate upon DNA. It is clear in the prior art that replicons and certain vectors have the ability to auto replicate. However, neither the prior art nor the specification teaches sequences that correspond to auto-replication function. Furthermore, the prior art teaches that in the broadest interpretation of auto-replication, all DNA sequences can auto-replicate. As there is no correlation between the structure of the recited sequences and their ability to confer auto-replication and given the diversity and large size of DNA sequences, and the inability to determine which will also auto-replicate, it is concluded that the invention must be empirically

determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

***Conclusion***

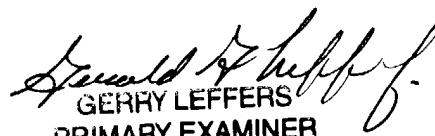
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD  
Examiner  
Art Unit 1636

April 23, 2004

  
GERRY LEFFERS  
PRIMARY EXAMINER